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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,091

01/16/2004

Thomas L. Cantor

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

08/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/760,091	Applicant(s) CANTOR ET AL.	
	Examiner JACOB CHEU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-71, 78-84, 86, 92, 93 and 95-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-68 and 98-107 is/are allowed.
- 6) ☒ Claim(s) 69-71, 78-84, 86, 92, 93, 95-97 and 108-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/14/07; 12/14/07; 12/14/07; 7/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

2. Applicant's amendment filed on 6/12/2008 has been received and considered. The following information provided in the amendment affects the instant application:

Claims 1-46, 72-77, 85, 87-91, 94 have been cancelled.

Claims 108-127 are added.

Claims 47-68 and 98-107 had been withdrawn.

Claims 69-71, 78-84, 86, 92-93, 95-97, 108-127 are under examination.

Priority

It is noted that Applicant claims priority based on its parent cases, i.e. US 09344039 (now US Patent 6743590) and US 09231422 (now US Patent 6689566). However, due to lack of support from the specification, the current application is accorded priority date based on its filing date, i.e. 1/16/2004 (See below New Matter Rejection).

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The rejections of claims 69, 71, 78-84, 86, 92-93, 95-97 and 108-127 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the instant claims 69, 78, 92 and 86 recite “an antibody binds to a bioactive, three-dimensional epitope of a parathyroid hormone (PTH) in PTH₁₋₈ or PTH₁₋₉ sequence, wherein said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three-dimensional epitope within a PTH fragment selected from a PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment”. No support from the specification can be found. Furthermore, no disclosure or data are disclosed concerning the “isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three-dimensional epitope within a PTH fragment selected from a PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment”.

It is noted that PTH₁₋₉ is also a new matter not supported by specification. The original specification amendment filed on 1/16/2004, at page 11, line 7, Applicant requested to enter SEQ ID No. 4 (human PTH 1-8 fragment) and SEQ ID No. 7 (rat PTH 1-8 fragment), where both the sequence has only 8 amino acid which spans from 1-8 of the PTH molecule (emphasis added). No 1-9 PTH fragment is disclosed. Additionally, although Applicant submitted Mr. Cantor's declaration (3/23/2007) indicating Figure 5 experiment was conducted by an PTH antibody purified by PTH 1-9 fragment (See page 2). However, it is not an obvious error falls into the category of remedial specification amendment under MPEP §2163- *“While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit,*

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or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).” There is no discussion or statement regarding the 1-9 PTH fragment throughout the specification. Rather 1-8, 1-6, 1-13PTH fragments are disclosed (See section 0035, 0038-39; original claims 62-63, 68, 72, 76-77). It is not an obvious error. Thus, it is still a new matter with regarding to PTH 1-9 fragment.

It is also noted that applicant claims a genus where an antibody “binds to a three-dimensional epitope of a PTH, wherein said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three dimensional epitope *within* a PTH fragment selected from a PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment ”. *In view of the specification, Applicant merely discloses 7-84 PTH fragment compared with whole 1-84 whole PTH (See Figure 11)* (emphasis added). The specification and the claims as original filed do not support binding affinity data with respect to the recited range, i.e. PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment compared to the whole PTH. The existing data of 7-84 PTH fragment is even outside of the recited range. Such claimed range now creates a genus of antibodies that bind a genus of epitopes that was not disclosed in the specification. See *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Thus, it is a new matter under 35 USC 112, first paragraph.

It is noted that Applicant also submits Dr. Lener’s declaration in support of the amendment. Examiner has considered the declaration and acknowledges the 3-dimensional epitope of the PTH. However, as discussed above, the newly amended claim creates an unsupported genus. Assuming *arguendo*, the declaration filed by Dr. Lener (3/23/2007) is part of the specification, which includes 1-8, 1-9, 1-10, 2-9, 1-34 PTH fragment where the data indicating these fragments indeed have lower affinity to the antibody than that of the whole PTH (See Exhibit 1-5 data from declaration; Note, 1-5, 1-

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6 and 1-7 and 7-84 PTH fragment are not within the recited starting range, i.e. 1-8 PTH fragment)(emphasis added). Nevertheless, these species (1-8, 1-9, 1-10, 2-9, 1-34) do not constitute sufficient representative number of the whole genus, i.e. from PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment. It has been held that a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Taken together, the instant claims now recite a limitation which was not clearly disclosed in the specification and recited in the claims as originally filed.

Response to Applicant's Arguments

Although applicant in the Remarks indicates the inherent characteristics of the antibody, particularly at page 8, line 24-25 and Figure 11. Applicant also relied on Dr. Lerner's binding assay for support of the instant amendment. It is noted that in the whole specification, only Figure 11 shows data referring to higher affinity of the antibody to the whole PTH (1-84) versus the fragment (7-84). As discussed above, there is only **ONE** PTH fragment versus whole PTH in binding affinity to the antibody was disclosed in the present specification (note, page 8, line 24-25 is merely the description of Figure 11). Examiner also pointed out that fragment 7-84 PTH is even outside the recited range of PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment (emphasis added). No disclosure of affinity of any other fragments, such as 1-8, 1-9....to 1-34 PTH fragment compared to the whole (1-84) PTH is disclosed.

In the Remarks, page 14, Applicant argues that Dr. Lerner's binding analysis fulfills inherency principle outlined by the MPEP section 2163.07 (a). *"By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter."*

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Furthermore, Applicant argues that the binding assay on Exhibit 3 supports the newly amended features, particularly “said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three-dimensional epitope within a PTH fragment selected from PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment”.

Applicant's arguments have been considered, but are not persuasive.

Following the same quotation of MPEP 2163.07 (a), “To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). The antibody was purified from the serum of the animals immunized with the PTH molecule, i.e. polyclonal antibody. Thus far, assuming Dr. Lener's data are part of specification, Applicant merely present ONE example of using this polyclonal antibody for binding assay (See Exhibits 2-5). This is “not necessarily present” in the whole genus commensurate with the claimed scope and would not be “so recognized by persons of ordinary skill” governed by the inherency principle, particularly coupled with insufficient representative number species (See above MPEP 2163.07 (a)).

Applicant also provides Fiskin et al. reference (J Biol Chem 1977 Vol. 252, page 8261-8) in supporting the three-dimension epitope assertion. Examiner acknowledges the notion, but the instant amendments still raise "new matter" issue (See Remarks, page 16-17).

Conclusion

3. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641